K132224

8.0 510(K) SUMMARY

Date Prepared: July 3, 2013

8.1 SUMMARY OF SAFETY AND EFFECTIVENESS

Submitted By: Lee Alexander
President
Unimed Surgical Products, Inc

8.2	Trade/Proprietary Name:	Unimed Surgical Coated Electrosurgical Electrodes
8.3	Common/Usual Name:	Electrosurgical Electrodes
8.4	Classification Name:	Electrosurgical, Cutting & Coagulation & Accessories
8.5	Manufacturing Facility Address:	Unimed Surgical Products, Inc. 1041 Belcher Road Largo, FL 33777
	Establishment Registration Number:	1058746
8.6	Sterilization Facility Address:	Food Technology Service, Inc. 502 Prairie Mine Road Mulberry, FL 33860
	Establishment Registration Number:	1054811
8.7	Classification:	Class: II Panel: General and Plastic Surgery Product Code: GEI Cite: 21 CFR 878.4400

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8.8 Substantial Equivalence

Unimed Surgical Coated Electrosurgical Electrodes are substantially equivalent to the Unimed Coated Laparoscopic/ Arthroscopy/ Suction-Irrigation Electrode (K970066) and the Unimed Coated Needle Electrode/Coated Blade Electrode/Coated Ball Electrodes (K962935)

8.9 Technological Characteristics

Unimed Surgical Coated Electrosurgical Electrodess have the same technological characteristics as the current marketed product.

8.10 Performance Data

Verification testing of the electrodes was performed sufficient to confirm that the products meet their specifications.

8.10.1 Physical Testing
- 8.10.1.1 Minimum Coating Adhesion - ≥ 3.5 lbs.
- 8.10.1.2 Pull Test - Attachment to Pencil – compliant with IEC 60601-2-2 –Minimum 10-lbs Pull Force

8.10.2 Coating Testing
- 8.10.2.1 Performance and integrity of the coatings of aged devices were confirmed at Normal and Extreme use conditions.

8.10.3 Electrical Testing per IEC 60601-2-2
- 8.10.3.1 Dielectric Strength
- 8.10.3.2 Hipot Testing

8.10.4 Biological Specifications

8.10.4.1 Biocompatibility

Patient contact materials (coatings and insulation) on the Unimed Coated Electrodes meet the requirements of ISO 10993-1

8.10.4.2 Color Additives

Color additives are listed as GRAS and are non-toxic in the Code of Federal Regulations.

8.10.5 Shelf Life

The performance of the electrodes was confirmed following accelerated aging to the expiration date using the Arrhenius Model.

8.11 Conclusion

Unimed Surgical concludes, based on the information presented, that the new coated product lines are substantially equivalent to products currently marketed legally in the US.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Unimed Surgical Products, Incorporated
Ms. Lee Alexander
President
1041 Belcher Road
Largo, Florida 33777

October 8, 2013

Re: K132224
Trade/Device Name: Coated Electrosurgical Electrodes
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: September 30, 2013
Received: October 4, 2013

Dear Ms. Alexander:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: K132224

Device Name: Coated Electrosurgical Electrodes

Indications for Use: The Coated Electrosurgical Electrodes are intended for the following indications:

- Cutting of Soft Tissue
- Coagulation of Soft Tissue

Prescription Use ___X__ **AND/OR** **Over-The-Counter Use _____**
(Part 21 CFR 801 Subpart D) **(21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Long H. Chen -A

Digitally signed by Long H. Chen -A
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Long H. Chen -A, 0.9.2342.19200300.100.1.1=1300369056
Date: 2013.10.08 13:31:02 -04'00'

for MXM

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K132224